(>0.7) for the Physical domain, high (>0.5) for the Total score and the Living domain and moderate (>0.3) for the Cognition and Emotional domains. **CONCLUSIONS:** The BRAF-MDQ was completed well by participants, related to appropriate measures of disease severity, retained its factor structure, gave reproducible results and was responsive to clinical change, confirming its validity as a measure of RA fatigue.

PRM145

CDAD-DAYSYMS™: A NEW PATIENT-REPORTED OUTCOME TOOL FOR *CLOSTRIDIUM DIFFICILE*-ASSOCIATED DIARRHOEA

Kleinman L[1], Talbot GH[2], Schüler R[3], Broderick K[4], Revicki D[5], Nord CE[6]

[1]*Evidera, Seattle, WA, USA,* [2]*Talbot Advisors LLC, Anna Maria, FL, USA,* [3]*Actelion Pharmaceuticals Ltd, Allschwil, Switzerland,* [4]*Cubist Pharmaceuticals, Lexington, MA, USA,* [5]*Evidera, Bethesda, MD, USA,* [6]*Karolinska Institutet, Karolinska University Hospital, Stockholm, Sweden*

OBJECTIVES: Patient-reported outcome (PRO) measures provide relevant information on how patients function and feel about their health. Such data are useful in clinical practice and registrational trials. Despite the importance of symptom assessment in CDAD, there is no validated PRO for *Clostridium difficile*-associated diarrhoea (CDAD). A qualitative research study was conducted to develop a CDAD PRO according to US FDA PRO guidelines. **METHODS:** Content development comprised 2 study phases, with input from an advisory group of 6 CDAD experts in Europe and North America. Phase I elicited patients' experiences of CDAD symptoms in open-ended discussions during telephone interviews. Supplementary interviews obtained nurses' observations. A draft PRO was developed following demonstration of concept saturation. Readability and translatability were assessed. Phase II involved 2 rounds of patient interviews, with revision of the draft PRO after each round. All patients were ≥18 years old, with confirmed CDAD. IRB approval and participant informed consent were obtained. **RESULTS:** Phase I interviews included 18 patients and 6 nurses in the United States; 16 additional patients were interviewed in Phase II. Patients were representative of the general CDAD population, and diverse in age, gender, and disease severity. Concept saturation was reached in Phase I for spontaneously reported CDAD symptoms. Items were organised in a draft conceptual framework with 5 hypothesised domains: diarrhoea, abdominal discomfort, tiredness, lightheadedness, and other symptoms. Phase II demonstrated initial content validity of the 13-item draft daily diary (CDAD-DaySyms™). Participants reported the questions were clear, relevant, and comprehensive; were able to use the instructions to complete the diary correctly; and considered the 24-hour recall period appropriate. **CONCLUSIONS:** The CDAD-DaySyms™ captures symptoms relevant to CDAD patients, demonstrating initial content validity. To allow its use in clinical practice and CDAD clinical studies, final content and psychometric validity are being evaluated in 2 ongoing international clinical trials.

PRM146

DEVELOPMENT AND CONTENT VALIDITY TESTING OF A TREATMENT ACCEPTANCE MEASURE FOR USE IN HYPERCHOLESTEROLEMIA PATIENTS RECEIVING TREATMENT VIA SUBCUTANEOUS INJECTION

Tatlock S[1], Grant L[1], Arbuckle R[1], Khan I[2], Manvelian G[3], Sanchez R[3]

[1]*Adelphi Values Ltd, Bollington, UK,* [2]*Sanofi, Bridgewater, NJ, USA,* [3]*Regeneron Pharmaceuticals, Tarrytown, NY, USA*

OBJECTIVES: In phase II studies, alirocumab, a PCSK9 inhibitor administered via subcutaneous injection, demonstrated significant reduction in LDL-C levels. The objective of this study was to conduct qualitative research to explore the concept of treatment acceptance in patients receiving a subcutaneous injection to support the development and testing of a patient-reported outcome measure, the Injection-Treatment Acceptance Questionnaire (I-TAQ). **METHODS:** A literature review led to the targeting of 'treatment acceptance' as the measurement concept in preference to treatment satisfaction. Concepts generated from the literature and instrument review informed the drafting of 17 items in the I-TAQ; item wording was adapted from three validated instruments. Qualitative interviews were conducted among 29 US-English speaking patients participating in alirocumab's phase III program who self-administered the treatment via autoinjector (n=19) or pre-filled syringe (n=10). First, concept elicitation (CE) questioning was used to elicit concepts relating to patients' treatment experiences and acceptance. The I-TAQ was then cognitively debriefed using "think-aloud" methods. Verbatim transcripts were analyzed using thematic analysis and Atlas. ti. Revisions were considered after each round of interviews. **RESULTS:** Qualitative analysis of CE data indicated treatment acceptance to be high, with the following concepts identified as relevant: perceived efficacy, side effects, self-efficacy, convenience and overall acceptance. Ten (34%) patients reported an initial fear of needles, which subsided with no impact on discontinuation. Pain was not considered relevant by patients, suggesting no pain associated with the injection. Five items were added following round 1 interviews, three were retained after round 2 testing and two were added at finalization, forming the conceptually comprehensive 22-item I-TAQ. Patients demonstrated good understanding of item wording, instructions, response scales and recall period. **CONCLUSIONS:** Successive rounds of interviews resulted in a treatment acceptance measure with strong content validity. Next steps are to psychometrically validate the I-TAQ in a population with experience of taking alirocumab.

PRM147

THE INFLUENCE OF GENE EXPRESSION PROFILING (GEP) ON DECISIONAL CONFLICT IN CHEMOTHERAPY TREATMENT DECISION-MAKING FOR EARLY-STAGE BREAST CANCER (BRCA)

Marshall D[1], MacDonald K[1], Deal K[2], Trudeau M[3], Leighl N[4], Bombard Y[5]

[1]*University of Calgary, Calgary, AB, Canada,* [2]*McMaster University, Hamilton, ON, Canada,* [3]*Sunnybrook Health Sciences Centre, Toronto, ON, Canada,* [4]*Ontario Cancer Institute, Toronto, ON, Canada,* [5]*Li Ka Shing Knowledge Institute, St. Michael's Hospital, Toronto, ON, Canada*

OBJECTIVES: Individuals with BrCa have high decisional conflict with respect to treatment decisions. GEP of tumours informs risk prediction, potentially affecting decisions about adjuvant chemotherapy in early BrCa, where only 15% will experience recurrence. We aimed to examine whether GEP reduces decisional conflict in chemotherapy treatment decision-making. **METHODS:** We embedded the validated Decisional Conflict Scale (DCS) into our discrete choice experiment survey examining preferences for chemotherapy treatment in early BrCa. Of the 1004 general population participants, 200 completed the DCS before (DCS-1; no GEP test score in scenario) and after (DCS-2; GEP test score added to scenario) the discrete choice experiment. The 16-item DCS was scored from 0-100 with five subscores. Mean total and subscores, standard deviations and change in scores were calculated, with significance based on matched pairs t-tests ($p<0.05$). We anticipated GEP would decrease decisional conflict in individuals unsure of their chemotherapy treatment decision. **RESULTS:** As anticipated, total score and all subscores (uncertainty, informed, values clarity, support, and effective decision) decreased significantly (all $p<0.05$) in the group of respondents (n=33) who indicated uncertainty about taking chemotherapy in DCS-1 but changed to no chemotherapy after receiving a GEP test score in DCS-2. In the group of respondents (n=25) who indicated they would undergo chemotherapy in DCS-1 but changed to unsure in DCS-2, their effective decision subscore increase significantly (24.5 to 34.5, $p<0.05$). In the overall sample (n=200), total decisional conflict decreased from DCS-1 to DCS-2 by 0.5 ($p=0.3$) and all subscores had non-significant decreases with the exception of effective decision, which had a non-significant increase. **CONCLUSIONS:** GEP influences chemotherapy treatment decisional conflict in individuals who are initially unsure in their treatment decision-making. However, we do not observe this effect in individuals who do not change their chemotherapy treatment decisions.

PRM148

PATIENT REPORTED UTILITIES IN FIRST-LINE ADVANCED OR METASTATIC MELANOMA: ANALYSIS OF TRIAL CA184-024

Porter J[1], Lee D[1], Hertel N[2], Hatswell AJ[1]

[1]*BresMed, Sheffield, UK,* [2]*Bristol Myers Squibb, Uxbridge, UK*

OBJECTIVES: In oncology, the impact of interventions on health-related quality of life (HRQL) is traditionally modelled based on disease progression status. The aim of this analysis was to assess if more meaningful patterns exist in HRQL data, based on other clinically important events that should be considered in modelling utility. **METHODS:** HRQL data from the CA184-024 trial of ipilimumab plus dacarbazine in previously untreated patients with unresectable malignant melanoma were analysed. European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire Core-30 (EORTC QLQ-C30) responses were mapped to a generic, preference-based measure (EORTC-8D) by means of a published and validated mapping algorithm. The utility observations available for each patient were used to examine the relationships between HRQL and a number of disease- and time-based variables, including treatment effect, progression status and time to death, via a mixed effects regression model. **RESULTS:** Progression status was found not to be significantly predictive of utility ($p=0.29$). Of the variables considered, the strongest relationship was with time to death, the mixed effects model for which was significantly predictive of utility ($p\leq0.001$). HRQL dropped as patients approached death; patients treated with ipilimumab had a utility of 0.86 if time to death was more than 1 year, which reduced to 0.61 during the final month of life. The ipilimumab treatment variable was associated with a small negative coefficient (-0.02), accounting for the adverse event profile of the drug when added to dacarbazine ($p=0.06$). **CONCLUSIONS:** Analysis of the CA184-024 HRQL data showed that time to death rather than progression status was significantly predictive of utility. Hence, modellers should carefully examine primary data to determine if a time to event approach or a progression based approach is appropriate to model utility best reflecting the pathology of the disease.

PRM149

RASCH FIRST? FACTOR FIRST?

Chen WH, McLeod LD, Coles TM

RTI Health Solutions, Research Triangle Park, NC, USA

OBJECTIVES: Rasch modelling theory and its extensions have become popular tools in assessing psychometric properties of patient-reportedoutcome (PRO) instruments. Since the Rasch model assumes a unidimensional structure, it is important to assert that this assumption has not been violated. However, there has been much debate about using factor analysis as the first step to assess dimensionality or using the Rasch model directly to identify items not fitting the unidimensional model. This study uses simulated data to compare the two techniques to examine the unidimensional assumptions. **METHODS:** Simulated data that represent a typical PRO instrument are generated based on the following variables: sample size (200 or 400), number of factors (1,2, or 3), and correlation among factors (0.4 or 0.7). Each simulated PRO assessment contains 15 items with 5 response categories. Exploratory factor analysis is conducted, and the number of factors proposed by the results are noted. A Rasch model theory analysis is also conducted, and the number of mis-fit items is noted. The unidimensional test associated with Rasch model is also conducted. **RESULTS:** Preliminary results suggest that when there is one dominant factor, the Rasch results identify the simulated factor and it becomes the underlying trait. Items not belonging to the dominant factor are flagged as mis-fit items or as forming secondary factors based on the unidimensional test. In situations where there is no dominant factor, factor analysis is able to identify separate factors, whereas the results are inconsistent using Rasch model. **CONCLUSIONS:** Rasch first or factor first? The preliminary findings suggest that, when there is prior knowledge of a dominant factor, Rasch modelling can be conducted first and will result in a unidimensional measure. When there is no prior knowledge of a dominant factor, then factor analysis should be conducted first to examine the dimensionality.

PRM150

PREDICTING SUICIDAL BEHAVIOR IN VETERANS AND ACTIVE MILITARY PERSONNEL: POSSIBILITIES FOR ELECTRONIC DEPLOYMENT TO DISCOVER A PREDICTIVE ASSESSMENT

Sage CC[1], Platko JV[1], Nokela M[2]

[1]*Covance Market Access Services, San Diego, CA, USA,* [2]*Covance Market Access Services, Solna, Sweden*